IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER HEALTHCARE AG, ALCON, INC. and ALCON RESEARCH, LTD., Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., Defendant.	REDACTED PUBLIC VERSION Civil Action No. 06-234-SLR

PLAINTIFFS' POST-TRIAL BRIEF ON INFRINGEMENT

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After Defendant Teva Pharmaceuticals USA, Inc. ("Teva") filed ANDA No. 78-073 seeking to market a generic version of Vigamox®, a highly-effective and commercially successful ophthalmic antibiotic solution, Plaintiffs Alcon, Inc. and Alcon Research, Ltd. (collectively "Alcon") brought this suit for infringement of claim 1 of U.S. Patent No. 6,716,830 ("the '830 patent"), PTX 5. The active compound in Vigamox® is moxifloxacin.

The infringement issue in this case is very straightforward. Claim 1 claims:

> A topical ophthalmic pharmaceutical composition comprising moxifloxacin or a pharmaceutically useful hydrate or salt thereof in a concentration of 0.1 to 1.0 wt % and pharmaceutically acceptable vehicle therefor.

The only question is whether Teva's proposed generic product contains "moxifloxacin" as that term is used in claim 1; the parties have stipulated that Teva's product meets all the other limitations of the claim. *See* D.I. 79 at Ex. 1 ¶ 45.

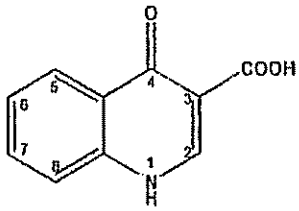
Teva does not dispute that the claim term "moxifloxacin" had a well-accepted meaning to the person of ordinary skill in the art ("POOS") as of September 30, 1998 At that time, moxifloxacin was the internationally recognized name for a particular chemical compound. It had by then been used in the literature repeatedly to refer to that particular compound, and was understood to mean only that compound.

Teva also does not dispute that its ANDA product contains moxifloxacin, as that term was and is commonly understood. Teva's only response is that because the '830 patent's specification contains a typographical error in the depiction of the structure of moxifloxacin, Alcon "redefined" moxifloxacin to mean a different compound. That is nonsense. Teva can only make its argument by focusing solely on one picture in the specification and ignoring the remainder of the paragraph containing this picture and the remainder of the patent and its file history, all of which make abundantly clear that there has been no redefinition. Indeed, the

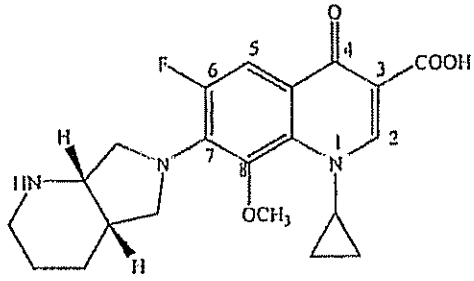
evidence is overwhelming and unrebutted that the POOS would have understood the '830 patent as a whole to disclose that moxifloxacin as used in claim 1 means the compound that all artisans understood to be moxifloxacin. Teva's product therefore infringes.

BRIEF TECHNICAL BACKGROUND

This case involves "quinolones," which are a class of antibacterial compounds that share certain features in common, namely their core chemical structure:



See PTX 2003; Tr. 54:13-55:2 (Taylor). The quinolone core structure has various positions at which atoms or chemical groups (called "substituents") may be attached. Those positions are numbered 1-8 in the figure above. The substituent attached to position 3, for example, is called the "3-position substituent." Nalidixic acid was the first recognized quinolone antibiotic and possesses, among other features, a carboxylic acid group at the 3-position, represented in the drawing above by "COOH." Tr. 55:11-25, 62:10-63:8 (Taylor). Quinolone antibiotics—which are derivatives of nalidixic acid—always possess a carboxylic acid at the 3-position. Tr. 55:14-25 (Taylor).[1] Moxifloxacin is a quinolone antibacterial, and has the following structure:



[1] As discussed below, the lone exception to this rule is where the 3-position substituent is an ester, which converts to the carboxylic acid after administration. *See infra* at p. 12.

See PTX 3, Claim 1; PTX 136 at 1706; PTX 2001.

Organic molecules, such as moxifloxacin, are three-dimensional entities. Although two compounds may have the same atoms connected in the same way, they sometimes have different orientations in three-dimensional space. Tr. 83:9-23 (Taylor). Such compounds are called "stereoisomers," and their orientation in space is depicted using various conventions and notations. In the example of moxifloxacin above, there are two bolded lines on the 7-position substituent. *See, e g*, PTX 2004; Tr. 82:24-83:23 (Taylor). That means that the carbon-hydrogen bonds shown extend upward from the plane of the page. Tr. 83:9-84:11 (Taylor). As a result, moxifloxacin has "S,S" stereochemistry; by contrast, the compound with the opposite stereochemistry—*i.e.*, the bonds pointing downward from the plane of the page—has "R,R" stereochemistry. Tr. 83:24-84:13 (Taylor). Two compounds having this mirror-image relationship are "enantiomers" of one another, Tr. 84:14-20 (Taylor), and a 50/50 mixture of the two enantiomers is termed a "racemate" or racemic mixture. Tr. 84:21-23 (Taylor). Generally, a racemic mixture is indicated by using specific notations such as "rac" or "DL." Tr. 86:15-23, 87:6-21 (Taylor).

ARGUMENT

I. TEVA'S ANDA PRODUCT INFRINGES CLAIM 1

A. The Legal Standard for Infringement.

The infringement inquiry is a two-part process: the first step is to construe the claims, and the second step is to compare the accused product to the construed claims and determine whether each element recited by a claim is present in the accused product. *Elbex Video, Ltd. v. Sensormatic Elecs Corp.*, 508 F.3d 1366, 1370 (Fed. Cir. 2007).

A court should construe a claim term according to "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Phillips v AWH*

Corp , 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc). The "starting point" for claim interpretation is the claims themselves. *Id.* Claim terms are presumed to carry their ordinary and customary meaning as understood by the POOS. *Phillips*, 415 F.3d at 1312; *Elbex*, 508 F.3d at 1371; *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir. 1999). In addition, the Federal Circuit has emphasized the importance of looking to how the specification would be understood by the POOS in ascertaining the meaning of a claim term, an inquiry in which expert testimony may provide valuable guidance. *Phillips*, 415 F.3d at 1315; *TiVo, Inc. v. Echostar Commc'ns Corp* , 516 F.3d 1290, 1306-07 (Fed. Cir. 2008) (affirming construction in accordance with term's ordinary meaning where the POOS "would 'readily understand'" that meaning "'upon a reading of the claim language and its context in the specification'"). The prosecution history should also be consulted, as it may bear on a term's construction. *Phillips*, 415 F.3d at 1317.

B. The Person of Ordinary Skill in the Art Would Have the Qualifications of a Microbiologist and/or an Ophthalmologist.

Because claim construction fundamentally depends on the POOS's understanding of a claim term in light of the specification, the initial inquiry concerns the identity of the POOS.

The Federal Circuit has identified several factors that may be relevant to determining the qualifications of the POOS: "(1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field." *Envtl. Designs, Ltd. v. Union Oil Co* , 713 F.2d 693, 696 (Fed. Cir. 1983). "Not all such factors may be present in every case, and one or more of these or other factors may predominate in a particular case." *Id.* at 696-97.

Application of these six factors demonstrates that the POOS would be a microbiologist

and/or ophthalmologist, not, as Teva suggests, solely a formulator (although the POOS would possess certain skills possessed by a formulator). First, the three named inventors of claim 1 of the '830 patent all have training in microbiology and worked in the field of ocular microbiology; not one is a formulator. Tr. 403:19-24 (Alfonso); 615:7-617:3 (Stroman). In addition, the '830 patent explicitly identifies that the problem it addresses relates to the art of treating and preventing ophthalmic infections, not formulating products (factor 2). Specifically, it focuses on the "need for improved compositions and methods of treatment [of ophthalmic infections] based on the use of antibiotics that are more effective than existing antibiotics against key ophthalmic pathogens, and less prone to the development of resistance by those pathogens." PTX 5, Col. 1, ll. 46-52; Tr. 251:1-22 (Allen); Tr. 404:8-23 (Alfonso); Tr. 831:11-833:11 (Zhanel).[2] The evidence established that an individual with training in microbiology and/or ophthalmology would possess the ability to evaluate whether an antibiotic had been found to address these problems, and specifically whether moxifloxacin was an appropriate choice (factor 6).[3] Tr. 403:2-15 (Alfonso); Tr. 834:6-837:10 (Zhanel). Indeed, workers in the field who were trying to address these problems were microbiologists or ophthalmologists. Tr. 403:2-15, 406:8-407:6, 411:14-412:6 (Alfonso); Tr. 834:5-836:3 (Zhanel); Tr. 569:2-571:1, 616:25-617:3 (Stroman).

Microbiologists and ophthalmologists had to undertake sophisticated analyses of a

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[2] The patent does not suggest or identify a problem in the art of formulation. PTX 5; Tr. 836:4-7.

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[3] Teva puts the cart before the horse by assuming that moxifloxacin had already been selected for use in a topical ophthalmic composition, thereby assuming away the very problem the '830 patent was designed to address. Tr. 244:4-245:11, 245:17-246:8 (Allen). As to the relevant question of selecting a compound for topical ophthalmic use, formulators have no involvement, and Teva's only expert, Dr. Allen—himself an accomplished formulator—admitted that he has never had involvement in the process of selecting an antibiotic for ophthalmic use. Tr. 242:1-5 (Allen); Tr. 411:14-412:6 (Alfonso); Tr. 616:20-617:3 (Stroman); Tr. 834:20-836:3 (Zhanel).

potential treatment's relative benefit in treating and preventing the particular infections of concern versus the likely toxicity associated with the treatment (factor 5). *See* Tr. 408:8-410:9 (Alfonso); Tr. 894:15-897:5 (Zhanel). And the process for solving problems in the field involved the evaluation of many antibiotics for potential ophthalmic use in order to try to find an appropriate one to select—a slow process which required the skills of a microbiologist or ophthalmologist (factors 3 and 4). *See, e.g.*, Tr. 565:8-17 (Stroman); *see also* Tr. 570:7-571:1 (Stroman) (Alcon tested over 100 compounds between 1990 and the September 1998 priority date); Tr. 834:5-836:3 (Zhanel).

Taken together, there can be no doubt that the '830 patent relates to the fields of microbiology and ophthalmology. The evidence established that the POOS would have a Ph.D. in microbiology and/or an M.D. degree with training in ophthalmology and, while the ability of the POOS would include preparing formulations, he or she would not have expertise solely in formulation as Teva asserts. Tr. 406:1-411:13 (Alfonso); Tr. 836:8-839:7 (Zhanel); *see also* PTX 2018. And the uncontested evidence was that a microbiologist and/or ophthalmologist would have the knowledge to comprehend the types of basic organic chemistry issues presented in the '830 patent, *i e.*, the ability to identify chemical structures and functional groups for quinolone antibiotics. Tr. 51:10-53:2 (Taylor); Tr. 413:11-21 (Alfonso); Tr. 838:8-839:24 (Zhanel).

C. The Person of Ordinary Skill in the Art Would Have Interpreted "Moxifloxacin" in Claim 1 in Accordance with Its Common Meaning.

There is no dispute that Teva's product contains moxifloxacin as that term would be understood by the properly defined POOS. **REDACTED**

; *see also* D.I. 79 at Ex. 1 ¶ 45. The infringement analysis therefore turns on whether "moxifloxacin" as used in claim 1 means something other than the common meaning of

moxifloxacin. Not surprisingly, the uncontroverted evidence was that the POOS would understand "moxifloxacin" as used in the '830 patent to mean "moxifloxacin," an internationally recognized compound with the specific chemical structure depicted above on page 2.

The evidence was overwhelming and undisputed that the claim term "moxifloxacin" had a clear meaning in September 1998, the '830 patent's priority date. *See* D.I. 79 at Ex. 1 ¶ 18. By that time, "moxifloxacin" had an established meaning to the POOS and was associated with the compound having the structure and stereochemistry depicted above, which has a specific chemical name. Tr. 57:3-58:3 (Taylor); PTX 2001; *see also supra* at p. 2. For instance, as of September 30, 1998, "moxifloxacin" was the International Nonproprietary Name ("INN") assigned by the World Health Organization ("WHO") to this compound.[4] *See* Tr. 58:13-60:23 (Taylor); PTX 138 at 266, 279; PTX 139 at 187-88; *see also* Tr. 171:7-8 (Allen) (moxifloxacin was a known chemical in 1998). The POOS would therefore have known that "[i]f you see the name moxifloxacin, you know that it has this chemical name and this structure" as identified by the WHO. Tr. 60:12-23 (Taylor); *see also* Tr. 63:21-64:3 (Taylor). Indeed, Alcon's expert Dr. Edward Taylor testified that in his entire six-decade career he had never seen anyone apply an existing INN to a new structure. Tr. 81:25-82:3 (Taylor).

Similarly, peer-reviewed literature available as of the priority date specifically associated the term "moxifloxacin" with the compound's chemical formula and structure. Tr. 64:4-66:25 (Taylor); PTX 135 at 797; PTX 136 at 1706; PTX 137 at 101. Therefore, the POOS "would know that [moxifloxacin] was a compound which was known and previously identified and had a specific recognized structure. In other words, the person of ordinary skill reading Claim 1 would

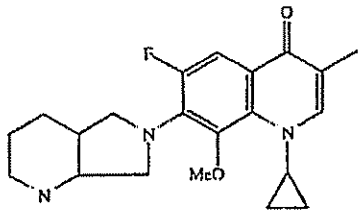
[4] INNs are published by the WHO as generic names for potential pharmaceutical compounds. Tr. 58:4-12 (Taylor). The WHO first circulates a proposed name for public comment and then publishes the recommended name, which is "the official internationally recognized name for that specific compound that is identified by that specific chemical name." Tr. 59:23-60:20 (Taylor).

know that—what moxifloxacin was." Tr. 67:16-68:7 (Taylor).

Teva offered no contrary evidence.[5] And, as discussed more fully below, the patent's specification and file history reinforce the only conclusion the POOS could reach upon review of the '830 patent: "moxifloxacin" as used in claim 1 has its ordinary and accepted meaning.

D. Teva's "Redefinition" Argument Is Baseless.

Teva argues that the '830 patent redefined moxifloxacin to be a different compound by stating, in Column 3, that "Moxifloxacin has the following structure:



"

PTX 5, Col. 3, ll. 38-48. Under Teva's theory, the patent, by depicting this structure, redefines moxifloxacin (1) to have a methyl group at the 3-position (indicated by a line) and (2) to be a racemic mixture of two enantiomers (rather than the S,S-enantiomer).

Teva is wrong. The issue regarding the interpretation of the claim term "moxifloxacin" is how the claim would be interpreted by the POOS in view of the specification as a whole and whether, viewed by the POOS in context, the specification contains a clear indication that redefinition of that commonly understood term was intended. The unrebutted evidence was that the POOS would not have understood the specification to have redefined moxifloxacin, but rather that the inventors intended the term "moxifloxacin" to carry its ordinary meaning.

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[5] Nor did Teva offer any evidence that its POOS would have a different understanding. Rather, Teva's expert was asked to assume that claim 1 was infringed (because moxifloxacin means the compound commonly known by that name). Consequently, he offered no opinion regarding the meaning of moxifloxacin to a formulator or the construction of claim 1. *See* Tr. 173:12-18 (Allen).

1. The Legal Standard for Redefinition of a Claim Term.

It is fundamental that in ascertaining the meaning of a claim, the specification is read through the eyes of the POOS, not through the lens of lawyers trying a case or a lay person having no background in the area. *Phillips*, 415 F.3d at 1313; *TiVo*, 516 F.3d at 1306-07. And the inquiry is not about what one snippet of the specification could be read to mean in isolation, but rather how the claim would be understood by the POOS upon review of the specification as a whole. *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1371-72 (Fed. Cir. 2005) (examining the entirety of the written description to ascertain whether the patentee had redefined a claim term); *Johnson*, 175 F.3d at 990-91 (same). For the specification to redefine a claim term, the specification as a whole must clearly "put one reasonably skilled in the art on notice that the inventor intended to redefine the claim term." *Merck*, 395 F.3d at 1370. Put another way, a claim term only can be redefined when the POOS, upon review of the entire specification, would understand the patentee to have intended to impart a definition that deviates from the ordinary meaning of the claim term. *Compare Abbott Labs. v. Andrx Pharms., Inc.*, 473 F.3d 1196, 1210-11 (Fed. Cir. 2007) (rejecting argument that specification redefined claim term in light of expert testimony showing that POOS would not have so interpreted the specification) *and Merck*, 395 F.3d at 1370, *with Cultor Corp. v. A.E. Staley Mfg. Co.*, 224 F.3d 1328, 1331 (Fed. Cir. 2000) (finding redefinition where specification as "understood by persons in the field of the invention" expressly limited the invention); *see also Agere Sys., Inc. v. Broadcom Corp.*, No. Civ.A.03-3138, 2004 WL 1658530, at *16 (E.D. Pa. July 20, 2004) (finding no redefinition because expert testimony demonstrated that POOS would not interpret language in specification as a redefinition) In the absence of a clear redefinition in light of the specification as a whole, "an inventor's claim terms take on their ordinary meaning." *York Prods., Inc. v. Cent. Tractor Farm & Family Ctr.*, 99 F.3d 1568, 1572 (Fed. Cir. 1996).

2. The Intrinsic Record Shows that "Moxifloxacin" Was Not Redefined.

a. The POOS Would Understand that the 3-Position Contains an Obvious Typographical Error.

Here, the intrinsic record is replete with evidence that verifies that the '830 patent uses "moxifloxacin" in accordance with its ordinary and accepted meaning, and that the single, isolated structure on which Teva relies contains an obvious typographical error. *See* Tr. 68:18-69:10 (Taylor); Tr. 839:9-24 (Zhanel). Indeed, the evidence regarding the meaning that a POOS would ascribe to the term "moxifloxacin" upon review of the entire specification was clear and unrebutted: the term "moxifloxacin" in the '830 patent means the quinolone compound by that name whose precise structure was well known by artisans at the priority date.

First, the specification states at the very outset that the patent relates to quinolone antibacterials. *See, e.g.*, PTX 5, Col. 1, ll. 22-29 (discussing the use of "quinolone antibiotics"); Tr. 69:12-70:9 (Taylor). As Dr. Taylor testified, all quinolone antibacterials have a carboxylic acid group at the 3-position. Tr. 72:10-73:23 (Taylor); PTX 161. It is for that very reason that quinolone antibiotics are often referred to as 3-quinolone carboxylic acids. Tr. 55:14-25, 69:12-70:9 (Taylor). Teva construes "moxifloxacin" in claim 1 as a compound that has a methyl at the 3-position, instead of a carboxylic acid. *See* Tr. 70:10-18 (Taylor); Tr. 839:9-21 (Zhanel). But under that construction, "moxifloxacin" would not be a quinolone antibiotic, notwithstanding the patent's express characterizations to the contrary. Thus, the POOS would not have read the patent to redefine moxifloxacin as having a 3-methyl substituent. *See* Tr. 72:1-6 (Taylor); Tr. 839:9-24 (Zhanel). Moreover, the undisputed evidence was that the POOS would have expected that a quinolone that lacked a 3-position carboxylic acid would not be active against bacteria. Tr. 72:1-6, 76:24-77:2, 79:3-14 (Taylor); Tr. 839:9-24 (Zhanel). Yet the data in the patent shows that "moxifloxacin" is in fact is active against bacteria, PTX 5, Col. 3, l. 66–Col. 4, l. 18; Tr.

76:12-23 (Taylor). This is still further reason that the POOS would not have read the patent to redefine moxifloxacin as a compound with a 3-methyl, but rather would have understood that the structure Teva relies on contains an obvious error and that "moxifloxacin" is meant to refer to the known, active quinolone antibiotic called moxifloxacin. Tr. 77:3-10 (Taylor).[6]

Second, immediately below the structure on which Teva relies, in the very same paragraph, the '830 patent states that "[f]urther details regarding the structure, preparation, and physical properties of Moxifloxacin and other compounds of formula (I) are provided in U.S. Pat. No. 5,607,942." PTX 5, Col. 3, ll. 49-51; *see also* Tr. 80:25-81:6 (Taylor). Teva ignores that contextual statement, as it wants to stop reading its purported "redefinition" once the structure it relies on is shown. The reference to the '942 patent, however, is crucial to the POOS's understanding of "moxifloxacin" because it means that moxifloxacin was a known molecule that previously had been disclosed in another reference---*i.e.*, the inventors did not intend to define a novel structure that does not belong to the class of quinolone antibiotics. Tr. 79:15-25 (Taylor). In fact, not only is the structure of moxifloxacin disclosed in the '942 patent, but that patent does not encompass a single compound with a methyl in the 3-position among the billions of quinolone antibiotics disclosed. PTX 3, Claim 1; *Id.* at Col. 1, l. 20--Col. 2, l. 25; Tr. 80:1-24 (Taylor). There is no indication whatsoever in the '830 patent that the invention relates to the use of a novel compound, never previously disclosed, to treat ophthalmic infections.

Third, consistent with the patent's disclosure that the invention relates to the use of

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[6] Teva asserts that because the '830 patent states that the invention is based "on the use of a new class of antibiotics," PTX 5, Col. 1, l. 19, the POOS would have believed that the structure Teva relies on could have antibacterial activity even though it lacks a 3-carboxylic acid. As Dr. Taylor explained, the POOS would understand "new class of antibiotics" to refer to the fact that moxifloxacin and the other quinolones referred to in the '830 patent employ a novel substituent at the 7-position Tr. 82:4-83:5 (Taylor); *see also* PTX 2004. Moreover, Teva's argument is inconsistent with the rest of the patent, which provides that the invention relates to using a known quinolone antibiotic to treat and prevent ocular infections. PTX 5, Col. 1, ll. 22-29.

quinolone antibiotics, the POOS would understand that the suffix "-oxacin" was defined by the WHO to mean that the compound belongs to the well-recognized class of quinolone antibacterials that possess a 3-position carboxylic acid. Tr. 61:17-63:15 (Taylor); PTX 152 at 21; *see also* Tr. 77:15-19, 77:23-78:4 (Taylor). In fact, not only do well-known quinolone antibiotics such as ciprofloxacin all contain the suffix "-oxacin," but there is no compound whose name contains the suffix "-oxacin" that is not a 3-quinolone carboxylic acid. Tr. 78:5-17 (Taylor) The POOS would thus understand from its name that "moxifloxacin" must have a 3-carboxylic acid.

Fourth, not only is Teva's argument at odds with the specification as a whole, it is refuted by the very structure on which Teva relies. That drawing uses the designation "Me" for the methyl in the 8-position methoxy group (a methyl attached to oxygen), but there is no "Me" depicted at the 3-position. PTX 5, Col. 3, ll. 38-48; Tr. 70:19-71:10 (Taylor). Because chemical structures are generally depicted using internally consistent nomenclature, the POOS would not view the line extending from the 3-position as a methyl, but rather as a chemical bond attached to a substituent that was inadvertently omitted. Tr. 69:2-10; 70:19-71:19 (Taylor).

Fifth, general formula I of the '830 patent requires that the 3-position be either (a) a carboxylic acid group, or (b) an ester, which is a pro-drug form of the active carboxylic acid functionality. PTX 5, Col. 2, l. 48–Col. 3, l. 35; Tr. 74:6-75:7 (Taylor). Moxifloxacin is stated to be the "most preferred" compound encompassed by that formula, PTX 5, Col. 3, l. 36; Tr. 75:14-76:1 (Taylor), a description supported by the originally-filed claims of the application, PTX 6 at BA001-0001583-85 (indicating that moxifloxacin is a compound within formula I); Tr. 619:9-21, 620:11-13 (Stroman). And the very paragraph on which Teva relies states that further details about moxifloxacin "and other compounds of formula (I)" are in the '942 patent—making

clear that moxifloxacin is a compound within formula (I) and cannot have a 3-methyl. PTX 5, Col. 3, ll. 49-51 (emphasis added). The specification thus further indicates to the POOS that the structure Teva focuses on contains a typographical error and that the inventors "just forgot to put the carboxylic acid group in." Tr. 76:2-11 (Taylor); *see also* Tr. 75:8-13 (Taylor).[7]

Finally, the file history of the '830 patent shows that the PTO understood the term "moxifloxacin" to mean the compound commonly known as moxifloxacin. During prosecution, the examiner initially rejected Alcon's claims and asserted that the antibiotics whose use Alcon was claiming were previously disclosed in the '942 patent. PTX 6 at BA001-002828. In response, Alcon agreed that the "moxifloxacin" used in its ophthalmic formulation was disclosed in the '942 patent. PTX 6 at BA001-2839. The examiner plainly understood that the inventors were claiming the use of the compound already known as moxifloxacin in a topical ophthalmic composition, not redefining moxifloxacin as some other compound. And that understanding accurately reflects the intent of the patentees. As one of the inventors, Dr. David Stroman testified, the inventors were claiming an ophthalmic composition containing the previously known compound moxifloxacin; they were not claiming "the use of a brand new compound in an ophthalmic composition." Tr. 618:17-619:2 (Stroman).

Teva did not offer a scintilla of evidence to refute any of the foregoing. The evidence is as clear as it is unrebutted: the POOS would have understood the patent to use the term "moxifloxacin" in accordance with its ordinary meaning. Tr. 81:16-23 (Taylor) (no possibility

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[7] Teva posits that the POOS might think that moxifloxacin was not part of formula I because it has a methoxy group at the 8-position, which Teva asserts is not encompassed by the general formula. However, as Dr. Taylor explained, formula I is supposed to be drawn with the substituent "A" at the 8-position—the result of another obvious typographical error—and "A" includes methoxy among the allowed permutations. Tr. 125:10-126:15 (Taylor), PTX 5, Col. 2, ll. 62 ("A is . . . C-OCH_3"). Indeed, the '942 patent, the reference to which the POOS is directed for information on the structure of moxifloxacin, PTX 5, Col. 3, ll. 49-51, uses "A" to represent the 8-position substituent, *see* PTX 3, Col. 1, ll. 20-30; Tr. 147:23-149:9 (Taylor).

that the POOS would understand the patent to be redefining moxifloxacin).[8]

b. The POOS Would Understand the Moxifloxacin of Claim 1 to Have the Stereochemistry of that Compound.

Teva's argument that the POOS would understand the '830 patent to redefine moxifloxacin as containing a racemic mixture of enantiomers is likewise baseless. Indeed, Teva presented no evidence at all that the structure in column 3 would be understood to be limited only to racemic mixtures, which in itself provides sufficient basis to reject its assertion.

To the contrary, the unrebutted evidence was that the POOS would understand that the use of the term "moxifloxacin" means that the structure possesses the S,S-stereochemistry of moxifloxacin, *i e* , it is not a racemic mixture. Tr. 87:6-21 (Taylor). As Dr. Taylor explained, the POOS would know that compounds which have stereochemistry (such as moxifloxacin) are sometimes drawn without depicting the stereochemistry—for example, as here, by describing a molecule with its INN. Tr. 85:6-21, 86:3-14 (Taylor). Dr. Taylor provided several examples of this principle, including one from the quinolone literature in which moxifloxacin was drawn without showing its stereochemistry. *See, e.g.*, PTX 140 at 258; *see also* PTX 141 at 266-67; Tr. 88:1-89:14, 90:11-91:22 (Taylor).

REDACTED

REDACTED

[8] This is not a case where the claims, which serve an important public notice function, contain an error or refer explicitly to a figure in the specification containing an error. The claims and the specification as a whole properly reflect that a particular known compound, moxifloxacin, is the active ingredient of the claimed formulation. However, even if the clear typographical error at issue were in the claim or a figure in the specification referenced in the claim, the Court could properly correct the error by construing the claim in accordance with its accepted meaning and the entirety of the intrinsic record. *See I.T.S. Rubber Co. v. Essex Rubber Co.*, 272 U.S. 429 (1926); *Advanced Med. Optics, Inc v. Alcon Inc.*, 361 F. Supp. 2d 370, 383-84 (D. Del. 2005).

REDACTED

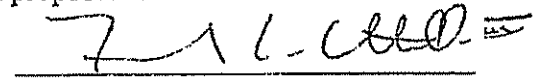
And finally, the evidence showed that if one wanted to describe a compound as a racemate, he or she would use specific nomenclature or other contextual information to do so, none of which was used here. *See* Tr. 86:15-23, 87:6-21 (Taylor).

RELIEF REQUESTED

Alcon requests that, pursuant to 35 U.S.C. § 271(e)(4)(A), the Court "order the effective date of any approval of" Teva's ANDA to be not earlier than expiration of the '830 patent, which is March 29, 2020, inclusive of pediatric exclusivity. *See also Ortho-McNeil Pharm., Inc. v. Mylan Labs., Inc.*, --- F.3d ----, 2008 WL 834402, at *6-7 (Fed. Cir. Mar. 31, 2008). Alcon also requests an injunction as set forth in Exhibit A.[9] Finally, Alcon seeks its costs. Fed. R. Civ. P. 54(d)(1); D. Del. L.R. 54.1(a)(1).

CONCLUSION

For the foregoing reasons, judgment should be entered in favor of Alcon and the remedies Alcon seeks should be ordered. A proposed Order is attached as Exhibit A.



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[9] *See* 35 U.S.C. § 271(e)(4)(B). The four factors set forth in *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006), support a permanent injunction here. With regard to irreparable injury and the inadequacy of monetary damages, the principal value of patents is their statutory right to exclude, and Teva's unlawful manufacture or sale of a generic version of Vigamox® in the face of Alcon's right to exclude others from doing so would constitute an irreparable injury that cannot be recouped through a monetary award. *See, e.g., Martek Biosciences Corp. v. Nutrinova Inc.*, 520 F. Supp. 2d 537, 558 (D. Del. 2007); *Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp.*, 397 F. Supp. 2d 537, 546-47 (D. Del. 2005). The balance of hardships tips in favor of an injunction as Alcon has prevailed and thus is entitled to exclude Teva during the term of the '830 patent, while the entry of an injunction simply maintains the status quo for Teva. *See Impax Labs., Inc. v. Aventis Pharms., Inc.*, 235 F. Supp. 2d 390, 396 (D. Del. 2002). Finally, the public interest is served when courts enforce valid patents. *Id.*

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Attorneys for Plaintiffs Alcon, Inc. and Alcon Research, Ltd.

CERTIFICATE OF SERVICE

I hereby certify that on May 1, 2008, I caused to be served by hand delivery the foregoing document and electronically filed the same with the Clerk of Court using CM/ECF which will send notification of such filing(s) to the following:

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I hereby certify that on May 1, 2008, the foregoing document was sent via Federal Express to the following non-registered participants:

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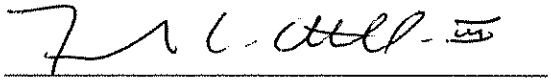

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EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER HEALTHCARE AG, ALCON, INC. and ALCON RESEARCH, LTD.,	)	
Plaintiffs,	)	
v.	)	C. A. No. 06-234-SLR
TEVA PHARMACEUTICALS USA, INC.,	)	
Defendant.	)	

[PROPOSED] FINAL JUDGMENT ORDER

The Court having conducted a trial in the above-referenced matter and having reviewed the parties' post-trial briefs, hereby enters judgment in the above-referenced matter as follows:

1. The drug product that is the subject of Defendant Teva Pharmaceuticals USA, Inc.'s ("Teva") Abbreviated New Drug Application ("ANDA") No. 78-073 infringes claim 1 of U.S. Patent No. 6,716,830 ("the '830 patent").

2. Claim 1 of the '830 patent is not invalid.

3. Pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any Food and Drug Administration approval of Teva's ANDA No. 78-073 shall be not earlier than March 29, 2020, the expiration date of the '830 patent (including pediatric exclusivity).

4. Pursuant to 35 U.S.C. § 271(e)(4)(B), Teva, its officers, agents, attorneys and employees, and those acting in privity or concert with any of them, are hereby enjoined from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any topical ophthalmic pharmaceutical composition within the scope of claim 1 of the '830 patent, including the drug product that is the subject of ANDA

No. 78-073, prior to March 29, 2020, the expiration date of the '830 patent (including pediatric exclusivity).

5. Judgment is hereby entered in favor of Plaintiffs Alcon, Inc. and Alcon Research, Ltd. (collectively "Alcon") and against Defendant Teva on Alcon's claim of infringement of claim 1 of the '830 patent.

6. Alcon is hereby awarded its costs in this action.

SO ORDERED this _____day of _____, 200__

_____
Sue L. Robinson
United States District Judge